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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,670	12/14/2001	Shmuel Sternberg	(DI-5763) 112713-136	2942

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EXAMINER	
SIEFKE, SAMUEL P	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,670	STERNBERG ET AL.	
	Examiner	Art Unit	
	Samuel P Siefke	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **34-38** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34-38 are directed to a method of providing dialysis therapy, but the claims only recite a method of detection and control.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1,3-8,10,11,15,17,20-23** are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1037045.

EP '045 discloses a quick acting toxic ammonia test for aqueous samples that comprises a porous (micorporous; 1.2 microns, page 3, line 9-11) hydrophobic membrane layer including a polymeric compound containing fluorine (polyvinylindene fluoride; page 3, line 4) and a pH sensitive dye (bromophenol blue; page 3, lines 22) embedded within the porous structure of the hydrophobic membrane layer. The membrane layer is capable of calorimetrically sensing the gas (page 2, lines 20-21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **25-38** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 1037045.

EP '045 discloses a quick acting toxic ammonia test for aqueous samples

EP '045 does not teach specifically of a pH sensitive dye embedded in the porous structure.

It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify EP '045 to embed the pH sensitive dye into the porous structure so the dye will not inadvertently be removed from the porous structure while monitoring the analyte. It would have been obvious to embed in all the pores in order to ensure complete reaction with the analyte. Regarding claim 25, providing an

aqueous solvent solution and immersing the hydrophobic membrane in the aqueous solvent such that the pH sensitive dye is embedded within the microporous structure of the hydrophobic membrane. It would have been obvious to one having an ordinary skill in the art to recognize that when a membrane is immersed in a solvent that both sides would be coated with the solvent containing the pH sensitive dye.

Claims **2, 9, 12-14, 16, 18, 19, 26-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1037045 in view of Ash (USPN 4,661,246).

EP '045 discloses a quick acting toxic ammonia test for aqueous sample as described above.

EP '045 does not teach the aqueous sample is a dialysate solution.

Ash teaches a dialysis instrument with dialysate side pump for moving body fluids. Ash teaches that a ammonia test strip is used for measuring the ammonia in the dyalysate liquid (col. 9, line 65-col. 10, line 53). It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify EP '045 for measuring dialysis solution in order to prevent leaching of potentially toxic chemicals (ammonia) to the dialysate via a gas permeable membrane.

Regarding the rate at which a reaction occurs on the test strip. This would have been obvious to produce a colorimetric reaction under 3 seconds in order for providing real-time analysis.

Claims **24** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1037045 in view of Werner, T., et al., Ammonia-sensitive Polymer Matrix Employing Immobilized indicator Ion Pairs," Analyst, Vol. I 20, June 1 995, pp. 1627- 1631.

EP '045 discloses a quick acting toxic ammonia test for aqueous sample as described above.

EP '045 does casting solution under acidic conditions to form the ammonia sensing membrane such that the pI-I sensitive dye is embedded within a microporous strucutre of the hydrophobic membrane.

Werner teaches using a casting technique to make a hydrophobic mebrane (page 1628). It would have been obvious to one having an ordinary skill in the art to modify EP '045 to use a casting techniqued to make the hydrophobic membranes because by using a casting technique, one can make any size of a hydrophobic membrane because casting allows one to have control of the thickness and shape of the membrane.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 703-306-0093. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Sam P. Siefke

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

December 12, 2003